REMARKS

The present communication responds to the Final Office Action of August 25, 2006 in which the Examiner rejected claims 10-17. Claims 2-9 remain withdrawn from consideration. Claims 15-17 were rejected under 35 U.S.C. § 112, first paragraph. Claims 10, 11, 13 and 14 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 4,846,791 ("Hattler et al."), claims 10-17 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,120,492 ("Finch et al.") and claim 12 was rejected under 35 U.S.C. § 103(a) as unpatentable over Hattler et al.

By the above amendments, claim 15 has been cancelled. Claim 10 has been amended to include the limitation of claim 15. Claims 10-14, 16 and 17 are pending in the application.

The claim rejections are traversed in view of the amendments and for at least the reasons articulated below.

Entry and reconsideration re requested.

Rejection under 35 U.S.C. § 112

Claims 15-17 were rejected under 35 U.S.C. § 112, first paragraph.

Applicant respectfully traverses the § 112 rejection.

The limitation of claim 15 has been incorporated into amended claim 10 and is directed to the cannula/needle combination of claim 10, wherein the cannula/needle combination is assembled prior to use.

Amended claim 10 is directed to a cannula/needle combination for a catheter head for administering a fluid substance, including a needle including a substantially sharpened piercing end, and a cannula surrounding the needle in a snug fit between an inner wall of the cannula and an outer wall of the needle, wherein a clearance is configured between the inner wall of the cannula and the outer wall of the needle, the fluid substance communicated in the clearance, thereby delivering the fluid without the needle being necessarily hollow, wherein the cannula/needle combination is assembled prior to use.

Claim 16 is directed to a method for administering a fluid substance including, inserting a pre-assembled cannula/needle combination by piercing the skin with the needle in cannula/needle combination, wherein the pre-assembled cannula/needle includes a needle comprising a substantially sharpened piercing end, and a cannula surrounding the needle in a snug fit between an inner wall of the cannula and an outer wall of the needle; wherein a clearance is configured between the inner wall of the cannula and the outer wall of the needle, the fluid substance communicated in the clearance, thereby delivering the fluid without the needle being necessarily hollow.

Claim 17 is directed to a system for providing a cannula/needle combination for a catheter head for administering a fluid substance, including piercing means for piercing the skin, wherein the piercing means includes at least a substantially sharpened piercing end, fluid delivery means for administering a fluid substance, wherein the fluid delivery means at least surrounds said piercing means and forms a snug fit between an inner wall of the fluid delivery means and an outer wall of the piercing means, wherein the piercing means and fluid delivery means are pre-assembled before piercing the skin, and wherein a clearance is configured between the inner wall of the fluid delivery means and the outer wall of the piercing means, the fluid substance communicated in the clearance, thereby delivering the fluid without the piercing means being necessarily hollow.

It is asserted in the Office action that claims 15-17 fail to comply with the written description requirement. Applicant submits that the specification reasonably conveys to one skilled in the art that the cannula/needle combination is assembled prior to use. The figures, particularly FIGS. 1 and 4, show the cannula/needle combination assembled prior to use on a patient. Furthermore, it is stated, "An object of this invention is to provide a cannula/needle combination for an insertion into the skin or subcutaneously which may be thin and yet still comprises and enhanced resistance to kinking." (Applicant's specification, page 2, lines 20-21.) Thus, it is the combination that is inserted into the skin, both the cannula and the needle together. As further noted, "The combination comprises an injection needle and a cannula surrounding the injection needle which is snugly fitted to the injection needle." (*Id.*, page 2, lines 28-30.) An advantage of the invention is significantly higher kinking stability. "[T]he needle does not

necessarily need to be hollow since the active substance is communicated between the outer cross-section of the needle and the inner cross-section of the cannula." (*Id.*, page 4, lines 8-10.) To have the kinking stability, the need for a "hollow needle with an opening is now eliminated. This opening is a mandatory requirement with the hollow needles in accordance with the prior art, however, to permit during priming transport of the active substance up to the tip of the cannula." (*Id.*, page 4, lines 12-14.) Since priming is done prior to use, and the priming can now be done without a hollow needle and with the cannula/needle combination of the present invention, the cannula/needle combination is therefore assembled prior to use as it is assembled prior to priming. Therefore, one skilled in the art would know that the needle and cannula are to be assembled prior to use.

Additionally, "[t]he piercing needle N with the surrounding cannula 1, which is preferably slightly expanded cross-sectionally by the piercing needle N and thus tensioned, will also be termed cannula/needle combination in the following." (*Id.* at page 4, line 30 to page 5, line 3.)

For at least the preceding reasons, the rejection of claims 15-17 under 35 U.S.C. § 112, first paragraph should be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 102

Claims 10, 11, 13 and 14 were rejected under 35 U.S.C. § 102(b) as anticipated by Hattler et al.

Applicant respectfully traverses the § 102(b) rejection.

Claim 10 has been amended to include the limitation formerly set forth in claim 15.

For a reference to be anticipated under 35 U.S.C. § 102(b), the reference must disclose each and every element of the claimed invention. Amended claim 10 is discussed above.

Hattler et al. discloses that "a multi-lumen catheter is formed by first introducing one end of an expandable tube into the blood vessel. A divider is then inserted into the distal end of the

tube and extends the length of the tube, thereby dividing the tube into a plurality of the separate lumens." (Hattler et al., Abstract.) Hattler et al. further discloses that the assembly is performed in steps and states, "one end of an expandable tube is first introduced into a blood vessel through an opening in the wall of the blood vessel. A divider is subsequently inserted from the distal end of the tube and extends the length of the tube." (Hattler et al., col. 2, lines 35-38.) The divider is *subsequently inserted* after the needle 20 is retracted.

> Figs. 4 through 8 illustrate the steps of installing a multi-lumen catheter in a blood vessel according to the present invention. Fig. 4 shows the first step in which the needle 20 and the end 12 of the catheter tube 10 are introduced into a blood vessel 40. The needle 20 punctures the wall 42 of the vessel and allows the end 12 of the catheter tube to be inserted through the needle into the interior of the blood vessel. A conventional hollow stainless steel needle of the type commonly used in the medical field is satisfactory for inserting the catheter tube into the blood vessel. . . .
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> . . . the needle 20 is then retracted out of the blood vessel, but the end of the catheter tube remains in place inside the blood vessel as shown in Fig. 5
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> . . . .
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> A divider 30 is then inserted into the catheter tube from the distal end 14 of the tube, as shown in Fig. 7.

(Hattler et al., col. 4, lines 4-46.) Hattler et al. does not disclose a needle/cannula combination that is assembled prior to use. The divider 30 in Hattler et al. is inserted into the catheter after the catheter has been inserted into the blood vessel. Therefore, divider 30 in Hattler et al., which examiner likens to Applicant's needle, is not a needle in a cannula/needle combination that is assembled prior to use as in amended claim 10. Therefore, Hattler et al. fails to disclose each of the elements of amended claim 10. Reconsideration and withdrawal of the § 102 rejection of the claims are respectfully requested.

Claims 10-17 were rejected under 35 U.S.C. § 102(e) as anticipated by Finch et al.

Amended claim 10 is discussed above. Finch et al. discloses methods and apparatus for percutaneously accessing an implanted port using an access cannula which is periodically

introduced to an aperture on an implanted port so that the cannula passes through the same tissue tract. (*See* Finch et al., abstract.) Finch et al. does not disclose a cannula surrounding the needle in a snug fit between an inner wall of the cannula and an outer wall of the needle, wherein a clearance is configured between the inner wall of the cannula and the outer wall of the needle, the fluid substance communicated in the clearance, thereby delivering the fluid without the needle being necessarily hollow as in claim 10. To the contrary, Finch et al. discloses an embodiment, wherein

> [a] penetrable seal 128 is positioned at the upper end of the passage 118 and permits removable entry of a stylet 130 having a sharpened distal end 132 which extends through the blunt end 122 of cannula 120. The stylet includes a handle 134 at its proximal end to permit removal the stylet after the cannula 120 has been introduced through a tissue tract to an implanted port.

(Finch et. al., col. 9, lines 13-19.) The stylet 130 is removed by a handle. (*See also*, Finch et al., FIG. 3a). Therefore, the stylet is utilized for initial tract formation. However, Finch et al. prefers use of an access cannula (16') which just uses a access needle 20 itself used as a penetrating element without utilizing a stylet as in FIG. 3a. (*Cf.* Finch et. al. FIGS. 3 and 3a.)

> A tissue penetrating element, which may be a needle, rod, stylet, tube, or virtually any other penetrating element, may then be introduced through the intact region of skin IR, as shown in FIG. 4G. In FIG. 4G, an access cannula 16' is used as the penetrating element, but it will be appreciated that this is not necessary for initial tissue tract formation. It is preferable, however, since use of an access cannula permits blood or other fluids to be exchanged through the implanted port from a time very shortly after implantation of the port. The penetrating element will be left in place transcutaneously through the skin for a time sufficient to at least begin forming the tissue tract, usually for at least one week, preferably for at least two weeks. After that initial time, the tissue penetrating element may be removed and the resulting tissue tract accessed using access cannulas according to the method of the present invention described above.

(Finch et al., col. 10, lines 50-59; see also, FIGS. 3 and 4G.) Not using the stylet is preferred, "since use of an access cannula *permits blood or other fluids to be exchanged* through the implanted port from a time very shortly after implantation of the port." (Finch et al., col. 10, lines 56-57 (emphasis added).)

Claims 16 and 17 are discussed above. Finch et al. does not disclose a method for administering a fluid substance or a system for providing a cannula/needle combination for a

catheter head for administering a fluid substance, wherein a clearance is configured between the inner wall of the cannula and the outer wall of the needle, the fluid substance communicated in the clearance, thereby delivering the fluid without the needle being necessarily hollow. Again, not using the stylet is preferred, "since use of an access cannula *permits blood or other fluids to be exchanged* through the implanted port from a time very shortly after implantation of the port." (Finch et al., col. 10, lines 56-57 (emphasis added).)

For at least the preceding reasons, the rejection of claims 10, 16 and 17 under 35 U.S.C. § 102(e) should be reconsidered and withdrawn.

Rejection of the Dependent Claims

Because claims 11 and 13-14 depend directly from independent claim 10, and incorporate all the limitations of the corresponding independent claim 10, they are allowable for the same reasons and, further, in view of their additional recitations.

Rejection under 35 U.S.C. § 103

Claim 12 was rejected under 35 U.S.C. § 103(a) as unpatentable over Hattler et al.

Claim 12 depends from amended claim 10. Claim 12 is directed to the cannula/needle combination of claim 10, wherein the cannula/needle combination is in fluid communication with a catheter. Amended claim 10 is discussed above. The § 103(a) rejection of claim 12 is traversed for the following reasons.

Nothing in Hattler et al. directs the skilled artisan or provides the requisite motivation for the skilled artisan to select a needle/cannula combination that is assembled prior to use as in amended claim 10. Furthermore, Hattler et al. discloses and teaches only a multi-step process for assembling a multi-lumen catheter that requires the catheter to be inserted into the blood vessel via a needle surrounding the catheter, removing the needle, and then inserting a divider into the catheter, it teaches away from the recited invention, even if a catheter is in fluid communication with the Hattler et al. arrangement. (*See* Hattler et al., FIGS. 4-8.)

Therefore, reconsideration and withdrawal of the § 103(a) rejection of claim 12 are

requested.

Conclusion

The Commissioner is hereby authorized to charge any deficiencies and credit any overpayments associated with this paper to Deposit Account No. 04-1420.

This application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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